Panel study Ultra Fine Particles Schiphol

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational non invasive

Summary

ID

NL-OMON44219

Source
ToetsingOnline

Brief title
not relevant

Condition

- Bronchial disorders (excl neoplasms)

Synonym
asthma, shortness of breath, wheezing

Research involving
Human

Sponsors and support

Primary sponsor: RIVM
Source(s) of monetary or material Support: RIVM

Intervention

Keyword: lung health, ultra fine particles

Outcome measures

Primary outcome

Lung function (FVC, FEV1, PEF and MMEF) for school panel

Lung function (FEV1, PEF) for asthma panel

NO in exhaled air for school panel

Resipratory symptoms (both panels)

Bronchodilator use (both panels)

Secondary outcome

not applicable

Study description

Background summary

Recent measurements of air pollution by TNO, RIVM and ECN in the vicinity of Schiphol airport showed considerably elevated air pollution concentrations several kilometers away from the airport. Particularly ultrafine particles (UFP) are elevated, related to rising and landing airplanes. UFP can penetrate deep in the lungs. The health consequences of these elevated UFP concentrations are difficult to quantify because of the difference in chemical composition between UFP from aircraft emissions and UFP from especially motorized traffic. In outdoor air, industry and especially motorized traffic are major sources of UFP. The societal commotion in the Schiphol region led the ministry of Infrastructure and Environment to order RIVM to define and coordinate a package of research studies to investigate the health effects of short-term and long-term exposure to ultrafine particles in the Schiphol region. The current panel study is part of this package and will focus on short-term effects on respiratory health of children. Children are a sensitive subgroup for air pollution effects.

Study objective

The objectives are to study short-term changes in lung function, exhaled NO, respiratory symptoms and bronchodilator medication use in association with short-term changes in UFP in general and UFP from aircraft emissions

specifically in children aged 7-11 year.

Study design

The study is a panel study, implying repeated observations of respiratory health in two groups of primary school children. The study has two components, (A) a school panel and (B) an asthma panel. Daily air pollution concentrations are obtained from monitoring stations at the two schools and detailed dispersion modelling for school and homes.

(A) School panel: Weekly supervised observations of respiratory health at school will be made in a group of 150 unselected 7 - 11 year old children of two schools in the Schiphol region. The schools will be selected to the north (east) and south (west) of Schiphol airport such that the airport is affecting one but not the other school on most days. This design allows us to separate potential health effects related to UFP from aircraft emissions and UFP in general. Every week a technician will visit the school during school hours to perform supervised spirometry and an exhaled NO measurement, a non-invasive airway inflammation assessment. At home, daily recording of respiratory symptoms and bronchodilator use in a daily diary and lung function will be performed. Each child participates for three months.

(B) The asthma panel consists of 50 7 * 11 year old children with asthma in the wider Schiphol airport region. They also participate for three months. At home, daily recording of respiratory symptoms, bronchodilator use in a daily diary and lung function will be performed. The asthma panel is added to the school panel to increase the number of children with asthma-like symptoms, necessary to be able to study potential effects of ultrafine particles on symptoms such as wheeze and shortness of breath and bronchodilator medication use.

The study as a whole will take place in a period of around 9 months.

Study burden and risks

Total participation time for a child in the study is three months. Each participant of the school panel will perform supervised tests of lung function and exhaled NO once a week at school, taking about 10 minutes each week. At home, a short diary will be filled out daily, under parental supervision, taking 2-3 minutes. Twice daily a simple lung function measurement will be performed, taking about 2 minutes. The children of the asthma panel will only perform home spirometry and daily symptom recording. There is no risk involved in participating. Participants do not personally benefit from the outcomes of the panel study. Children happily perform lung function tests after initial encouragement and explanation, and when they understand the technique they experience it as challenging and fun. In our experience, participating for 3

months is reasonable, people who start participating will almost always complete the required period. At the end of the study period a 25 euro gift certificate will be given and at regular intervals we will hand out small presents at school (home for the asthma panel) for encouragement.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

A: 150 subjects, criteria: joining the selected schools and aged 7 - 11
B: 50 subjects, criteria: having asthma, living near airport and aged 7 - 11

Exclusion criteria

none

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-12-2017
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	19-09-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL62313.041.17